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510(k) Summary

AUG 24 2006

CryoCath Technologies Inc.

SurgiFrost® *XL* Cryosurgical Device and Cryosurgical Console

1. SPONSOR

CryoCath Technologies Inc.
16771 Chemin Ste-Marie
Kirkland, Quebec
H9H 5H3, CANADA
Contact Person: Flor del Pilar Arana,
Director Regulatory Affairs and Official Correspondent
Telephone: 514-694-2380 ext 358

Date Prepared: July 25th, 2006

2. Device Name

Device Trade Name: SurgiFrost® *XL* Surgical CryoAblation System
Common/Usual Name: Cryosurgical system
Classification Name: Cryosurgical Unit and Accessories
Device Classification: Class II

3. PREDICATE DEVICES

CryoCath Technologies - SurgiFrost® Cryosurgical System (K021010, K040690 and K053436)

Endocare Inc. - CryoCare Cardiac Surgical System (K011040)

CryoMedical Sciences - AccuProbe 450, Accuprobe 550/530, Accuprobe 600 series (K973190)

4. DEVICE DESCRIPTION

The SurgiFrost® *XL* Cryosurgical Device and Cryosurgical Console are intended for minimally invasive cardiac surgical procedures, including the treatment of cardiac arrhythmias. The SurgiFrost® *XL* Cryosurgical Device and Cryosurgical Console freezes the target tissue and blocks the electrical conduction pathways by creating an inflammatory response or cryonecrosis.

The Intended Use does not change as a result of this special 510(k) submission.

The SurgiFrost® *XL* Cryosurgical Device and Cryosurgical Console and accessories act together as a System. The system is composed of the following components:

- Cryosurgical Control Panel and Power Cord
- Cryosurgical Console
- Tank Carrier
- Gas Tank Regulator and Wrench
- Gas Hose
- SurgiFrost® *XL* Cryosurgical Device (Single Use)
- Footswitch (optional)

The SurgiFrost® Cryosurgical System consists of a compact, easy-to-operate Cryosurgical Console and associated accessories that include SurgiFrost® *XL* Cryosurgical Probe to deliver cold temperatures to the targeted tissue. The control console operates off standard 120/230 VAC (60/50 Hz) wall power and utilizes inert argon gas. The Cryosurgical Console controls a single-use, disposable SurgiFrost® Cryosurgical Probe.

5. INTENDED USE

The SurgiFrost® *XL* Cryosurgical Device and Cryosurgical Console are intended for minimally invasive cardiac surgical procedures, including the treatment of cardiac arrhythmias. The SurgiFrost® *XL* Cryosurgical Device and Cryosurgical Console freezes the target tissue and blocks the electrical conduction pathways by creating an inflammatory response or cryonecrosis.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The SurgiFrost® *XL* Cryosurgical Device and Cryosurgical Console is substantially equivalent to the predicate devices based on intended use, design, technological, and operational characteristics. The differences between the CryoCath devices are minor and raise no new issues of safety or effectiveness.

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7. PERFORMANCE TESTING

Information submitted in this premarket notification for the SurgiFrost® *XL* Cryosurgical Device and Cryosurgical Console is substantially equivalent to the predicate devices listed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2008

Cryocath Technologies, Inc.
c/o Mr. Fred Milder
US Agent
Applied Physics
204 Clinton Rd
Brookline, MA 02445

Re: K062140
Trade/Device Name: SurgiFrost XL Cryosurgical Device, Model 60SFXL
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical Unit and Accessories
Regulatory Class: II (two)
Product Code: OCL
Dated: July 25, 2006
Received: July 27, 2006

Dear Dr. Milder:

This letter corrects our substantially equivalent letter of August 24, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

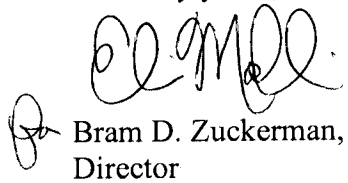
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062140

Device Name: *SurgiFrost® XL Cryosurgical Device and Cryosurgical Console*

Indications For Use: The SurgiFrost® *XL* Cryosurgical Device and Cryosurgical Console is intended for minimally invasive cardiac surgical procedures, including the treatment of cardiac arrhythmias. The SurgiFrost® *XL* Cryosurgical Device and Cryosurgical Console freezes the target tissue and blocks the electrical conduction pathways by creating an inflammatory response and cryonecrosis.

Prescription Use __X__ AND/OR Over-The-Counter Use___
(21CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Mechanick

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K062140